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Nos. 95-754, 95-886

Supreme Court, U.S.
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IN THE
Supreme Court of the United States
OCTOBER TERM, 1995

MEDTRONIC, INC.

Petitioner and Cross-Respondent,

v.

LORA LOHR AND MICHAEL LOHR

Respondents and Cross-Petitioners.

On Writ of Certiorari to
the United States Court of Appeals
for the Eleventh Circuit

BRIEF *AMICUS CURIAE* OF TRIAL LAWYERS FOR PUBLIC JUSTICE, P.C., IN SUPPORT OF LORA LOHR AND MICHAEL LOHR

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BRIEF *AMICUS CURIAE* OF TRIAL LAWYERS FOR PUBLIC JUSTICE, P.C., IN SUPPORT OF LORA LOHR AND MICHAEL LOHR

INTEREST OF *AMICUS CURIAE*

With the consent of the parties, as reflected in letters filed with the Clerk pursuant to Rule 37.3(a), *amicus curiae* Trial Lawyers for Public Justice, P.C. ("TLPJ"), hereby submits this brief in support of cross-petitioners/respondents Lora Lohr and Michael Lohr.

TLPJ is a national public interest law firm devoted to representing people injured by corporate or government illegality. TLPJ is supported by and utilizes the services of more than 1,500 trial lawyers throughout the United States and has represented many plaintiffs in cases against manufacturers of dangerous products. TLPJ is the only public interest firm in the nation dedicated to the preservation of the States' individual tort systems as the surest, and often sole, means of compensation to people injured by defective products.

Accordingly, TLPJ has often participated, as primary or

amicus counsel, in state and federal trial and appellate cases in which the preemption doctrine was a pivotal issue. As in those cases, the manufacturer of the dangerous product in this action seeks to thwart the proper functioning of the tort system through the misapplication of preemption doctrine.

SUMMARY OF ARGUMENT

I. For a decade after the adoption of the Medical Device Amendments (MDA) in 1976, medical device manufacturers did not even argue that the statute preempted state common-law damages claims. Their failure to raise preemption defenses is entirely understandable, for the text of the MDA does not expressly refer to the preemption of common-law claims; the legislative history is similarly silent on the subject; the FDA, which administers the statute, has construed it as *not* preempting state-law claims for damages; and Congress itself — by continuing to consider proposals to confer tort immunity on manufacturers that comply with the MDA — has indicated its understanding that it does not share Medtronic's view of the statute.

Tellingly, manufacturers began to raise preemption as a defense in medical device litigation not after any statutory change, or new disclosures about Congress' intent — for there were none — but rather after the since-rejected decision of the U.S. Court of Appeals for the Third Circuit in *Cipollone v. Liggett Group, Inc.*, 789 F.2d 181 (3d Cir. 1986), *rev'd in part and aff'd in part*, 505 U.S. 504 (1992), which unduly expanded the preemptive reach of the federal cigarette warning-label statutes. This Court corrected the Third Circuit's erroneous reasoning, but not before it infected construction of the MDA. As a result, many lower courts are now finding state common-law claims *expressly* preempted when those present at the MDA's enactment properly understood that such claims were not preempted at all.

II. This Court should make clear that the MDA does not expressly preempt state common-law damages claims. The reference to state-law "requirement[s]" in 21 U.S.C. § 360k(a)

pertains to positive-law enactments, not tort suits.

Medtronic has attempted to reduce the questions presented in this case to the following dichotomy:

> Did Congress, recognizing the dangers of over-regulation by the states, leave design issues to federal experts, who may authorize or proscribe the marketing of particular designs and employ a variety of remedial tools to cope with any problems discovered after marketing begins? Conversely, did Congress fear under-regulation at the federal level, leaving in place tort claims that allow juries and judges in fifty states to determine, after the fact, whether a particular design authorized for marketing by the federal experts falls beneath a state law standard of care?

Br. for Pet. Medtronic, Inc. at 2.

The dichotomy posited by Medtronic is a false one. There is no reason to think that Congress conceived of state common law as competing with a system of federal regulation. Positive-law enactments such as statutes, ordinances, and regulations address future conduct. Such enactments are backed by the coercive force of government and leave no room for choice. Tort law, by contrast, looks backward: despite its secondary deterrence function, tort law's primary goal is to compensate victims of past conduct. *E.g.*, William Prosser and Page Keeton, PROSSER & KEETON ON TORTS § 1 at 5, 7 (1984) ("[Tort law] is directed toward the compensation of individuals . . . . its primary purpose is to compensate for the damage suffered, at the expense of the wrongdoer."). Moreover, an tort action for damages does not "require" a defendant to change its conduct in the future, because it leaves the defendant free to pay damages and continue its conduct unaltered.

There is no inherent conflict between the regulatory goals of federal statutes and the principally compensatory goals of state tort law. In fact, the principally compensatory goals served by tort law are completely different from the regulatory goals served by statutes.

Accordingly, absent an explicit statement of congressional

intent to the contrary, this Court should recognize, as a presumptive matter, that Congress does not intend to displace the compensatory element of state tort law. This presumption should be particularly compelling where Congress has not itself provided a parallel mechanism for compensation, for it is difficult to believe that Congress would leave injured persons without a remedy. *See English v. General Electric Co.*, 496 U.S. 72, 85 (1990); *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984).

Moreover, there are powerful reasons to think that Congress did not intend the kind of immunity sought by Medtronic. Such an immunity would weaken manufacturers' incentive to develop safer products and would eliminate the important information-gathering function of the tort system. Furthermore, matters of compensation are not within the expertise or jurisdiction of regulatory agencies like the FDA. To hold that regulatory acquiescence supersedes all tort liability supposes that Congress intended to centralize all authority in the FDA for judging not only scientific issues but also for balancing the interests of injured consumers. Congress plainly did not design such a system.

Medtronic's reliance on *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), is entirely misplaced. In that case, this Court recognized that "there is no general, inherent conflict" between regulation and state common law damages actions. *Id.* at 518. Indeed, the holding of the majority opinion in *Cipollone* was that a 1965 statute providing that "[n]o statement relating to smoking and health shall be *required* in the advertising of [properly labeled] cigarettes" did not extend to common-law claims for damages.

Medtronic instead relies on the decision of the *Cipollone* plurality that tort claimants could not bring common-law claims challenging the effectiveness of congressionally drafted and mandated cigarette warnings under the 1969 statute. But this reasoning confirms that the MDA does not preempt common-law claims, because — in contrast to the 1969 cigarette statute — the MDA leaves ample room for manufacturer choice in designing, manufacturing, packaging, and labeling medical devices.

III. This case presents this Court with the opportunity to clarify several important principles of preemption law: (1) that there is no inherent conflict between federal consumer protection statutes and state tort law because the former are concerned principally with prospectively regulating harmful behavior, while the latter is tied primarily to the goal of compensation; (2) that express preemption analysis must be confined to a close textual inquiry that honors rather than disregards congressional intent; and (3) that implied preemption inquiries must similarly be limited, particularly where Congress has addressed the matter of preemption in the statute.

Common-law tort actions and state positive-law enactments should not readily be equated. Preemption analysis must proceed with the recognition that, when Congress decides to oust state law, particularly law that has been venerated for centuries, it does so with great care and precision — with a scalpel, not a meat axe.

ARGUMENT

There is an urgent need for this Court to clarify preemption doctrine in order to curtail what have become essentially freewheeling judicial exercises showing little regard for the handiwork of Congress or the constitutional interests of federalism. The treatment of the MDA in the lower courts exemplifies the danger of this trend.

I. LOWER COURTS HAVE EXTENDED THE PREEMPTIVE EFFECT OF THE MDA FAR BEYOND ITS PROPER SCOPE

1. The MDA was adopted in 1976. For more than a decade afterward, no medical device manufacturer even raised preemption as a defense to a damages claim, according to the reported cases.[1] The reasons are not hard to fathom:

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[1] In *National Women's Health Network v. A.H. Robins*, 545 F. Supp. 1177,

• The text of the MDA contains no express reference to preempting state-law damages claims.[2]

• "A careful perusal of the entire legislative history reveals no mention of preempting state common law tort claims." Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 MO. L. REV. 895, 923 n.128 (1994). Quite apart from the traditional rule that "a court appropriately may refer to a statute's legislative history to resolve statutory ambiguity,"[3] recourse to legislative history is useful because a striking omission from the legislative record — like the dog that did not bark — can itself be telling evidence. *See New York State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 115 S. Ct. 1671, 1681 (1995) (refusing to find preemption because "there is not so much as a hint in [the statute's] legislative history or anywhere else that Congress intended to squelch these state efforts").

• The FDA, whose views are entitled to deference under *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), recognized that the MDA does not preempt "State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (*e.g.*, requirements such as general electrical codes and the Uniform Commercial Code (warranty of fitness)) or to unfair trade practices in which the requirements are not limited to devices." 21 C.F.R. § 808(d)(1). If the MDA does not preempt general bodies of *positive law*,

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1181 (D. Mass. 1982), the defendant argued that the MDA preempted any state court authority to order a worldwide notification and recall campaign for the Dalkon Shield, but tellingly did not raise a preemption defense with respect to the plaintiffs' claims for damages.

[2] We discusss 21 U.S.C. § 360k(a) in Part II, *infra*.

[3] *Toibb v. Radloff*, 501 U.S. 157, 162 (1991); *see also Bank One Chicago, N.A. v. Midwest Bank & Trust Co.*, 116 S. Ct. 637, 644 (1996) (Stevens, J., concurring); *Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597, 610 (1991); Stephen Breyer, *On the Uses of Legislative History in Interpreting Statutes*, 65 S. CAL. L. REV. 845, 860-61 (1992).

such as the UCC, then *a fortiori* it does not preempt generally applicable bodies of state tort law. Thus, the FDA has issued an advisory opinion — which is binding on the agency pursuant to 21 C.F.R. § 10.85(e) — outlining the Commission's view that the MDA does not displace common-law claims.[4]

• Since adopting the MDA, Congress has repeatedly evinced its understanding that the statute does not displace common-law claims. For example, when it amended the MDA in 1990, *see* Pub. L. No. 101-629, 104 Stat. 4511, Congress provided that a medical device "user facility," whenever it becomes aware that a medical device has caused a serious injury or death, must submit a "user report" of the death or injury to the Secretary of Health and Human Services. 21 U.S.C. § 360i(b). The accompanying legislative history expresses Congress' understanding that patients injured by medical devices would have the right to sue the manufacturer.[5] Indeed, over the past two decades, Congress has considered numerous proposals to bar tort claims against medical devices that have received FDA premarket approval — proposals which would have been wholly unnecessary if Medtronic's view of the statute were correct.[6]

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[4] *See* Letter from Joseph P. Hile, Associate Commissioner for Regulatory Affairs, Food and Drug Administration, to Robert E. Manchester, National Women's Health Network (Mar. 8, 1984), reprinted at Pet. App. 4a-6a in *Lohr v. Medronic, Inc.*, No. 95-886.

[5] *See* H.R. Rep. No. 808, 101st Cong., 1st Sess. 21 (1990) ("The FDA is prohibited from disclosing the identity of medical device user facilities that file reports, except in very limited circumstances. The reports may not be admitted into evidence or otherwise used in any civil actions involving private parties. *However, there is no prohibition on civil litigation about the events that are the subject of the report.*") (emphasis added).

[6] *E.g., Hearings on S. 1400, the Product Liability Reform Act, Before the Subcommittee on the Consumer of the Senate Committee on Commerce, Science, and Transportation*, 101st Cong., 2d. Sess. 1 (1990) (statement by Sen. Bryan that Congress has been grappling with "controversial" product liability issues "for a good many years"); *id.* at 5 (statement by Sen. Gorton that the issue of product liability "is not new. . . . The debate heats up when the different factions — business, consumer groups, lawyers — attempt to

Not surprisingly, therefore, for at least ten years after the MDA's adoption, the "prevailing view" was that "a manufacturer's failure to comply with an FDA standard generally triggered a finding in court of negligence *per se* against the manufacturer, but the manufacturer's compliance with an FDA standard provided little protection against tort claims of a plaintiff." Adler & Mann, *supra*, 59 MO. L. REV. at 916.[7]

For example, in *Wooderson v. Ortho Pharmaceutical, Inc.*, 681 P.2d 1038, 1055, 1057 (Kan.), *cert. denied*, 469 U.S. 965 (1984), the Kansas Supreme Court upheld an award of punitive damages against a manufacturer despite its compliance with FDA-approved labelling. Similarly, in *O'Gilvie v. International Playtex, Inc.*, 821 F.2d 1438 (10th Cir. 1987), *cert. denied*, 486 U.S. 1032 (1988), the Tenth Circuit affirmed a multimillion-dollar judgment against a tampon manufacturer in a toxic shock syndrome case. Rather than framing an explicit preemption defense, the manufacturer contended merely "that its compliance

craft a solution"); *id.* at 315 (statement by Sen. Kasten that bills had been modified to eliminate "[c]ompliance with [FDA] standards defenses for compensatory damages . . ., an issue that we have discussed which was contentious").

Because such proposals have proved extremely controversial, in recent years proponents have scaled back the proposed immunity to bar the imposition of only *punitive* damages against products that comply with FDA requirements. *E.g.*, 141 Cong. Rec. S6453 (May 10, 1995) (statement of Sen. Dodd) (discussing provision of S. 565, the Product Liability Fairness Act of 1995, creating exemption from punitive damages for compliance with FDA standards). Even these more modest provisions have failed to pass Congress. Hence, according broad preemptive effect to the MDA would by judicial fiat grant medical device manufacturers a far greater immunity than they have ever been able to secure through the legislative process.

[7] *E.g.*, Jeffrey N. Gibbs & Bruce F. Mackler, *Food and Drug Administration Regulation and Products Liability: Strong Sword, Weak Shield*, 22 TORT & INS. L.J. 194, 243 (Winter 1987) ("Under current law, compliance with the FDA's requirements affords only modest protection against the successful lawsuit."); Frederick H. Fern, *FDA Standards Are Not the Final Word*, 14 THE BRIEF 24 (Spring 1985) (discussing imposition of punitive damages despite compliance with FDA requirements).

with FDA standards entitled it to judgment as a matter of law." *Id.* at 1443. The court of appeals dismissed that argument.

2. Manufacturers began to assert preemption defenses in medical device cases not after any revelation about the statute or Congress' intent, but after the since-rejected decision of the Third Circuit in *Cipollone v. Liggett Group, Inc.*, 789 F.2d 181 (3d Cir. 1986), *rev'd in part and aff'd in part*, 505 U.S. 504 (1992), regarding the federal cigarette warning-label statutes. The Third Circuit held state tort actions preempted, on the ground that they would upset Congress' "carefully drawn balance between the purposes of warning the public of the hazards of cigarette smoking and protecting the interests of the national economy." 789 F.2d at 187.[8]

Before this Court had the opportunity to repudiate the Third Circuit's reasoning by limiting use of implied preemption analysis and by reaffirming that "there is no general, inherent conflict between federal pre-emption of state warning requirements and the continued vitality of state common law damages actions," 505 U.S. at 518, the Third Circuit's faulty strain of preemption analysis in *Cipollone* had infected the interpretation of the MDA. Relying explicitly on the cigarette cases, lower courts began to find that a special FDA-prescribed warning label for tampons preempted claims challenging the efficacy of that warning. *See, e.g., Lindquist v. Tambrands, Inc.*, 721 F. Supp. 1058, 1063 (D. Minn. 1989) ("[T]he medical device cases are very similar to the cigarette cases. . . . From [Congress'] carefully wrought balance is inferred a legislative intent to preempt state law warning claims."); *Rinehart v. International Playtex, Inc.*, 688 F. Supp. 475, 477 (S.D. Ind. 1988) (relying on *Palmer v. Liggett Group, Inc.*, 825 F.2d 620 (1st Cir. 1987)).

[8] Within a year, the First and Eleventh Circuits issued similar decisions. *Palmer v. Liggett Group, Inc.*, 825 F.2d 620 (1st Cir. 1987); *Stephen v. American Brands, Inc.*, 825 F.2d 312 (11th Cir. 1987).

Not all courts made this mistake,[9] and even the courts finding failure-to-warn claims preempted recognized that state-law claims based on the design, composition, and construction of tampons were not displaced.[10] Moreover, the tampon labeling cases were distinguished by an unusual feature: the FDA had mandated a special consumer warning label,[11] an approach the FDA has

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[9] *E.g.*, *Kerns v. International Playtex, Inc.*, No. C-1-86-297 (S.D. Ohio Apr. 15, 1988); *Muzatko v. International Playtex, Inc.*, No. 85-C-1540 (E.D. Wis. May 14, 1987); *Peters v. J&J Products, Inc.*, No. 842-00765 (Mo. Cir. Ct. May 3, 1988). Other lower courts rejected preemption defenses in early IUD cases. *E.g.*, *Callan v. G.D. Searle & Co.*, 709 F. Supp. 662, 664 (D. Md. 1989); *Kociemba v. G.D. Searle & Co.*, 680 F. Supp. 1293, 1299 (D. Minn. 1988); *Tetuan v. A.H. Robins Co.*, 738 P.2d 1210, 1232-33 (Kan. 1987).

[10] *E.g.*, *Moore v. Kimberly-Clark Corp.*, 867 F.2d 243, 246-47 (5th Cir. 1989); *Rhinehart*, 688 F. Supp. at 477-78.

[11] In 1982, in response to a discovered association between toxic shock syndrome ("TSS") and tampons, the FDA adopted special labeling regulations for tampons mandating that the following consumer information appear "prominently and legibly in a package insert or on the package in terms understandable by the layerson[:]"

(1) the warning signs of TSS and what to do if the warning signs appear;

(2) the statistical risk of TSS to women using tampons;

(3) the advisability of using tampons with the minimum absorbency needed to control menstrual flow;

(4) the potential for avoiding the risk of getting tampon-associated TSS by not using tampons and the potential for "possibly reducing" the risk of getting TSS by alternating tampon use with sanitary napkin use during menstrual periods;

(5) the need to seek medical attention "before again using tampons if TSS warning signs have occurred in the past, or if women have any questions about TSS or tampon use."

21 C.F.R. § 801.430(d). If the above information was provided in a package insert, then the following "alert statement" was required to appear "prominently and legibly" on the package label:

ATTENTION: Tampons are associated with Toxic Shock

taken only for tampons, hearing aids, and a handful of other products. There is nothing comparable to this specific FDA action in this case.

3. Nonetheless, the stage was set for further defective preemption analysis. After this Court curtailed implied preemption analysis in *Cipollone*, lower courts began explicitly to equate positive-law enactments (like state regulations and statutes) with common-law actions and to hold that the MDA *expressly* preempted state-law claims for damages,[12] both in the context of premarket approvals (PMAs) issued by the FDA under 21 U.S.C. § 360e(c)(1), and in the context of the much less rigorous "substantial equivalence" standard of § 510(k). *See id.* at §§ 360e(b)(1)(B), 360c(f)(1)(A).[13]

Thus, lower courts are now finding as *expressly* preempted state-law claims that those present at the MDA's enactment understood were not preempted at all. It is highly implausible, to say the least, that a statute long accepted as having no preemptive effect on common-law claims can be said to contain a "clear and manifest" congressional statement to displace those claims in the wholesale fashion that Medtronic seeks. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

Syndrome (TSS). TSS is a rare but serious disease that may cause death. Read and save the enclosed information.

21 C.F.R. § 801.430(c).

[12] *See, e.g.*, *Slater v. Optical Radiation Corp.*, 961 F.2d 1330 (7th Cir.), *cert. denied*, 505 U.S. 917 (1992); *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.), *cert. denied*, 114 S. Ct. 84 (1993); *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir.), *cert. denied*, 114 S. Ct. 86 (1993).

[13] *See, e.g.*, *Duvall v. Bristol-Myers-Squibb Co.*, 65 F.3d 392, 399-400 (4th Cir. 1995).

II. THE MDA DOES NOT EXPRESSLY PREEMPT STATE-LAW CLAIMS FOR DAMAGES

The MDA does not expressly refer to state-law damages claims, except insofar as it provides that compliance with FDA recall and similar orders *does not* relieve manufacturers from liability in damages actions. 21 U.S.C. § 360h(d). The provision cited by Medtronic provides that (1) "no State or political subdivision of a State" may (2) "establish or continue in effect" (3) "any requirement" (4) "with respect to a device" that (5) is "different from, or in addition to, any requirement applicable under this chapter to the device," and "relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." 21 U.S.C. § 360k(a).

This statutory language does *not* expressly displace any state common-law claims for damages:

(1) The phrase "State or political subdivision of a State" reflects that Congress was referring to positive state law, not to common-law claims. This is not a phrase that Congress would have used to refer to the bodies that issue or apply the common law. Although the term "state law" may include common law as well as statutes and regulations, *Cipollone*, 505 U.S. at 522 (plurality opinion), neither a court nor a jury in a state court case (much less a jury in a federal court case applying state law) is typically referred to as a "State or political subdivision of a State." By comparison, when legislation is signed into law, when regulations are promulgated, or when ordinances are adopted, it is often said that "a State" (or a county or city) has changed its law. That terminology simply is not used when a jury applies the common law to the facts of a particular case.

(2) States do not "establish or continue in effect" requirements by means of the common-law tort system. The general norms embodied in the common law have been "established" over hundreds of years. Nor do individual verdicts "continue in effect" any form of requirements. Indeed, because compensation, rather than injury prevention, is the primary purpose of tort law, tort actions are not ordinarily structured to

provide specific guidance to manufacturers on precisely how to alter their conduct. A manufacturer is simply found negligent or otherwise liable.

(3) The word "requirement," read in context, plainly refers to positive enactments, not common law claims. The word is used three times in § 360k(a). In two instances,[14] it unquestionably means positive enactments, not court actions for damages. Only once, in the reference to state-law requirements, is the word even arguably ambiguous. It is "a basic canon of statutory construction that identical terms within an Act bear the same meaning." *Estate of Cowart v. Nicklos Drilling Co.*, 505 U.S. 469, 479 (1992).

(4) Common-law claims do not establish or continue requirements "with respect to a device" at all, because a defendant is always free — indeed, sometimes is expected — to pay damages rather than to modify its conduct. The only action ever *required* by a tort claim is the payment of a damages judgment — not action *with respect to a device*. Thus, a defendant is always able to comply with the federal requirement *and* to pay compensation to those injured by its misconduct. There is no possibility of incompatible legal commands in ordinary damages suits, and Medtronic's footnoted claim to the contrary is simply inaccurate. Br. of Pet. Medtronic at 46 n.24.[15]

Moreover, common-law claims do not impose requirements "with respect to a device," because they draw upon generally applicable norms — the duty not to deceive, the duty to behave non-negligently — that were not developed with reference to medical devices and that may be applied differently by different

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[14] 21 U.S.C. § 360k(a)(1) ("any *requirement* applicable under this Act"); *id.* at § 360k(a)(2) ("a *requirement* applicable to the device under this Act").

[15] There is no "actual conflict" or physical "impossib[ility]," Br. of Pet. Medtronic, Inc. at 46 n.24, between federal regulation of health and safety risks and state tort liability with respect to injuries that regulation has not prevented. The experience with FDA-approved drugs demonstrates that there is no such incompatibility.

factfinders in different cases.

(5) For the same reason, common-law claims do not establish or continue any requirement with respect to the device that is "different from, or in addition to, any requirement applicable under [the MDA] to the device" or that "relates to the safety or effectiveness of the device." Common-law claims focus primarily on compensating injured persons, not on prospectively deterring harmful conduct. As this Court has recognized — unanimously — the concept of "relating to" cannot be "taken to the furthest stretch of its indeterminacy," in the preemption context. *New York Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 115 S. Ct. 1671, 1677 (1995). If it were, "then for all practical purposes pre-emption would never run its course, for '[r]eally, universally, relations stop nowhere.' But that, of course, would be to read Congress's words of limitation as mere sham, and to read the presumption against pre-emption out of the law whenever Congress speaks to the matter with generality." *Id.* (citation omitted).

The rule that § 360k(a) does not preempt common law claims is neither unworkable nor threatening to the ability of medical device manufacturers to do business. It merely applies in the field of medical devices the same relationship between regulation and tort liability that exists under the statute to which the MDA was an amendment — the Food, Drug, and Cosmetic Act of 1938 (FDCA), a statute that has always been construed as permitting consumers to bring state-law damages claims for injuries caused by unsafe drugs, foods, or cosmetics. *E.g.*, *Merrell Dow Pharmaceuticals, Inc. v. Thompson*, 478 U.S. 804, 811 (1986) (suit against drug manufacturer arises under state rather than federal law and "is a subject traditionally relegated to state law").

The text, structure, and legislative history of the MDA reveal not even a hint of congressional intent to place devices in such a drastically different position from other products regulated under the FDCA. There is no logical reason to think that Congress would have wanted to do so. In fact, longstanding legal principles that form the background understanding against which Congress legislated make it impossible to ascribe the broad

preemptive effect to the MDA that Medtronic seeks.

A. TORT LAW, UNLIKE REGULATORY STATUTES, PRIMARILY FOCUSES ON COMPENSATING INJURED VICTIMS

Medtronic contends that, in passing the MDA, Congress "had to choose" into which of two categories state common-law actions fell: "a useful supplement to [Congress'] own safeguards against unsafe and ineffective devices" or "an unnecessary restriction that might impede its goal of promoting device innovation and availability." Br. of Pet. Medtronic, Inc. at 4. Medtronic ignores a third (and the most obvious) possibility: that Congress treated common-law damages actions as having little to do with its regulatory system because they serve primarily compensatory goals that are entirely separate from the matters addressed by the MDA.

1. Although tort law has incidental deterrent effects, its principal purpose is to compensate injured victims.[16] "'Over the centuries the common law of torts has developed a set of rules to implement the principle that a person should be compensated fairly for injuries caused by the violation of his legal rights.'" *Heck v. Humphrey*, 114 S. Ct. 2364, 2370 (1994) (citation omitted). The tort system operates on a retrospective basis. Each case requires an examination of the particular facts regarding a particular victim and a particular tortfeasor. "Tort law is tied to the goal of compensation . . . ." *Bennis v. Michigan*, No. 94-8729, 1996 U.S. Lexis 1565, * 47 n.13 (Mar. 4, 1996) (Stevens, J., dissenting); *see also Simon & Schuster, Inc. v. New York Crime Victims Bd.*, 502 U.S. 105, 118 (1991)

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[16] *See, e.g.*, Stephen Breyer, REGULATION AND ITS REFORM 176 (1982) (explaining that tort law has deterrent effects, but that "the common law, as administered by the courts, may reflect certain noneconomic or moral factors that will make it difficult to use shifts in common-law liability to achieve basically economic ends").

("Every State has a body of tort law serving" its "compelling interest" in "ensuring that victims . . . are compensated by those who harm them.").

By contrast, statutes and regulations are typically prospective in nature and focus not on compensating persons for injuries already sustained but on preventing socially harmful activities. "Regulation is not designed to provide or account for compensation" to the victims of dangerous products and their families. Mary Lyndon, *Tort Law and Technology*, 12 YALE J. ON REG. 137, 172 (1995). Safety standards can only attempt to head off similar deaths or serious injuries in the future.

2. The difference between the tort and regulatory systems means that a congressional decision to prevent States from adopting conflicting positive-law enactments is entirely different from a decision to curtail the compensatory function of tort law. Even if a State cannot alter a product's design, it should be able to provide a judicial system that resolves claims for wrongful injuries to its citizens and decides that, as between a manufacturer and an injured party, the manufacturer ought to bear the cost of compensating for those injuries that it could have prevented. To hold otherwise conflates the distinct elements of the tort system: its primary function in providing compensation and its secondary function in supplementing the deterrent effect of regulations.

Recognizing the important distinction between regulation and the tort system, this Court has traditionally held that statutes like the MDA do not cut off victims' rights to fair compensation under state law. In *United Construction Workers v. Laburnum Construction Corp.*, 347 U.S. 656 (1954), for example, this Court observed:

> Congress has neither provided nor suggested any substitute for the traditional state court procedure for collecting damages for injuries caused by tortious conduct. For us to cut off the injured respondent from this right to recovery will deprive it of its property without recourse or compensation. To do so will, in effect, grant petitioners

> immunity from liability or their tortious conduct. We see no substantial reason for reaching such a result.

Id. at 663-64.

In *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984), this Court held that the comprehensive scheme of federal regulation of nuclear energy facilities pursuant to the Atomic Energy Act of 1954 did not preempt a state-law claim for punitive damages arising from conduct relating to radiation hazards. This Court reasoned that:

> there is no indication that Congress even seriously considered precluding the use of such remedies either when it enacted the Atomic Energy Act in 1954 and or when it amended it in 1959. This silence takes on added significance in light of Congress' failure to provide any federal remedy for persons injured by such conduct. *It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct.*

Id. at 251 (emphasis added). Accordingly, this Court determined that "Congress assumed that such [state-law] remedies would be available." *Id.*

Similarly, in *Goodyear Atomic Corp. v. Miller*, 486 U.S. 174 (1988), this Court distinguished, for purposes of preemption analysis, "direct state regulation" of safety matters from "the incidental regulatory effects" of damages awarded pursuant to a state workers' compensation law. *Id.* at 185. In *English v. General Electric Co.*, 496 U.S. 72 (1990), this Court held that state common-law damages claims for emotional distress were not preempted by federal nuclear energy law. The Court concluded that, although awards to former employees for emotional distress would attach "additional consequences" to retaliatory employer conduct and could lead employers to alter the underlying conditions that were the subject of employee complaints, such effects would be "neither direct nor substantial enough" to warrant preemption. *Id.* at 85.

To be sure, common-law claims can have an incidental

regulatory effect on a defendant's conduct. But the principal function of the tort system is compensatory. And many state laws have indirect "regulatory effects" on tortfeasors' conduct, yet this Court has ordinarily held them not preempted in the absence of a very explicit congressional statement that they be displaced. *E.g.*, *New York State Conf. of Blue Cross & Blue Shield Plans*, 115 S. Ct. at 1683 (ERISA does not preempt state surcharges on hospital patients covered by commercial insurance because "they affect only indirectly the relative prices of insurance policies, a result no different from myriad state laws in areas traditionally subject to local regulation, which Congress could not possibly have intended to eliminate."); *Gade v. National Solid Wastes Management Ass'n*, 505 U.S. 88, 107 (1992) (federal Occupational Safety and Health Act of 1970 pre-empts only state law that "constitutes, in a direct, clear, and substantial way, regulation of worker health and safety" and does not pre-empt "state laws of general applicability (such as laws regarding traffic safety or fire safety)," despite their demonstrable effect on occupational safety).

Only in certain special contexts, like labor law, has this Court held that incidental regulatory effects are sufficient to justify displacement of tort law. In *San Diego Building Trades Council v. Garmon*, 359 U.S. 236 (1959), for example, this Court held that a state common-law damages award was preempted by the National Labor Relations Act on the ground that neither federal nor state courts possess jurisdiction over claims based on activity that is "arguably" subject to §§ 7 or 8 of the NLRA. *Id.* at 245. *Garmon* has not been read broadly.[17] But more importantly for present purposes, *Garmon* involved a special "presumption *of* federal pre-emption" relating to the primary jurisdiction of the National Labor Relations Board. *See Brown v. Hotel Employees*, 468 U.S. 491, 502 (1984); *English v. General Electric Co.*, 496 U.S. at 86-87 n.8.

No such special labor-law rule is applicable here. Instead, in

[17] *See, e.g.*, *Vaca v. Sipes*, 386 U.S. 171, 181 (1967) (*Garmon* does not extend to suits alleging breach of duty of fair representation).

this case, there is a strong presumption *against* federal preemption. *E.g.*, *New York State Conf. of Blue Cross & Blue Shield Plans*, 115 S. Ct. at 1676. A decision by Congress to establish federal regulation does not overcome that presumption and preempt state tort law. Congress legislates with the traditional understanding that federal regulatory and state tort laws are complementary systems serving different interests.

B. THE COMPENSATORY GOALS OF TORT LAW COMPLEMENT RATHER THAN CONFLICT WITH THE REGULATORY GOALS OF FEDERAL CONSUMER PROTECTION STATUTES

The regulatory system and the tort system complement each other, with one system attempting to anticipate problems before they occur and the other providing relief when consumers suffer injuries. Indeed, there is significant cross-fertilization between the tort system and regulation. For example, information obtained in individual tort suits often informs the judgment of federal regulators about whether existing standards are adequate or whether new protections should be proposed. "Obtaining accurate, relevant information" often constitutes a "central problem" for an administrative agency, particularly one like the FDA, which lacks subpoena power. Stephen Breyer, REGULATION AND ITS REFORM 103 (1982); *see also id.* at 112 ("the information problem is central and endemic to the standard-setting process"). As one scholar has observed, tort litigation is "an important social learning mechanism" because it generates data about the risks of new technologies. Lyndon, *supra*, 12 YALE J. ON REG. at 176. "[T]ort law's signals contain necessary basic messages that are not delivered through any other medium," "offer[ing] advantages that we need to account for before preempting tort law." *Id.*

Reading regulatory statutes as preempting common-law claims for damages would sacrifice the important information-gathering function of the tort system. There is no need to speculate as to the significance of this function in the context of medical devices. The Dalkon Shield tragedy, which was a primary impetus for

passage of the MDA, amply demonstrates the value of the tort system:

> Robins' dishonesty regarding the efficacy of its device, its refusal to conduct adequate testing of the Dalkon Shield, its ignoring of numerous adverse reports from physicians, its attacks on the personal character of victims in product liability lawsuits, and, ultimately, its suppression and illegal destruction of damning evidence against it were uncovered only after years of product liability litigation, some of which was unsuccessful because of Robins' suppression of critical evidence. In fact, none of this evidence was sought, or discovered, by FDA.

Adler & Mann, *supra*, 59 MO. L. REV. at 944 (footnotes omitted).

C. REGULATORY AGENCIES LIKE THE FDA DO NOT ADDRESS MATTERS OF COMPENSATION

Many commentators have analyzed the problems of "regulatory capture" or "government failure" in the context of administrative regulation of health and safety risks.[18] In this case, there is an even more powerful reason for thinking that the MDA has nothing to do with a manufacturer's state-law damages liability: the FDA has no authority or institutional competence to

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[18] *See, e.g.*, Stephen G. Breyer & Richard B. Stewart, ADMINISTRATIVE LAW AND REGULATORY POLICY 130-31 (2d ed. 1985) ("Few students of the subject would share Dean Landis' optimism about the potential use of the administrative agency. Federal administrative agencies have been subjected to an increasing barrage of criticism emanating from a variety of philosophical and political positions. Economists are concerned with the inefficiency, waste, and shortages they see caused by certain kinds of regulation. . . . Consumer groups complain that regulation is ineffective."); Stephen Breyer, REGULATION AND ITS REFORM 185 (1982) ("The defects and difficulties inherent in the system make regulation a crude weapon of government intervention."); John D. Graham and Jonathan B. Wiener, RISK VS. RISK (1995) (noting often unintentional risk tradeoffs resulting from health and safety regulation).

weigh the interests of consumers in receiving fair compensation for device-caused injuries. The FDA's expertise lies instead in assessing medical safety and effectiveness. Yet the implied premise of Medtronic's position is that the FDA, in determining whether to allow a manufacturer to market a device, should consider — as one factor in the calculus — the impact on consumers of extinguishing their state-law entitlement to compensation in the event of injury. Plainly, the FDA does not consider, and Congress never intended it to consider, this factor in passing on the manufacturer's request for device approval. If the process were otherwise, the agency would be forced to notify the public of the preemptive effect that its proposed action would have on state common-law claims and receive comments on the wisdom of displacing state-law rights to compensation. In fact, the matter is never addressed in regulatory proceedings.

D. MEDTRONIC'S ARGUMENTS ARE UNAVAILING

1. Medtronic asserts that "[c]ommon law duties have as potent a regulatory effect as state legislative enactments." Br. of Pet. Medtronic, Inc. at 14. But that statement is demonstrably unsustainable. A defendant has no choice whether to comply with a statute or a regulation; the availability of cease and desist orders ensures compliance. By contrast, the essence of tort law is that a defendant is always free not to alter its conduct and simply pay damages. Indeed, under a system of strict liability, it is sometimes rational for a defendant to pay compensatory damages rather than to change the design of its product. *See, e.g.*, Stephen Breyer, REGULATION AND ITS REFORM 175 (1982); Steven Shavell, ECONOMIC ANALYSIS OF ACCIDENT LAW § 3.1, at 48-51 (1987).

As an empirical matter, few individual verdicts have "regulatory effect." The cases are legion in which manufacturers do not respond at all to jury awards, or respond only when hundreds or thousands of claims have been filed. For example, A.H. Robins began a campaign to inform women of the risks of the Dalkon Shield, and to encourage them to have it removed, only after years of product liability litigation. *See* Adler &

Mann, *supra*, 59 MO. L. REV. at 912 n.84, 944-45.

2. Medtronic also relies heavily on the plurality opinion in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), which indicated that the phrase "requirement[s] or prohibition[s] . . . imposed under State law" in the Public Health Cigarette Smoking Act of 1969 encompassed state-law tort claims. 505 U.S. at 521. But this decision provides no help to Medtronic.

First, in *Cipollone* this Court recognized that "there is no general, inherent conflict" between regulation and state common law damages actions. *Id.* at 518. Indeed, the *holding* of a majority of the Court in *Cipollone* was that the 1965 Federal Cigarette Labeling and Advertising Act "is best read as having superseded only positive enactments by legislatures or administrative agencies that mandate particular warning labels," 505 U.S. at 518 — even though the 1965 preemption provision regarding advertising provided that "[n]o statement relating to smoking and health shall be *required* in the advertising of [properly labeled] cigarettes." (emphasis added). Hence, *Cipollone* does not mean that any reference to state-law "requirements" automatically preempts common-law claims for damages. And there is no evidence that in 1976 Congress would have expected such an interpretive rule.[19]

Second, the special warning label at issue in *Cipollone* bears no resemblance to the regulatory structure of the MDA. In *Cipollone*, Congress itself drafted the specific warning statements that were required to be included on cigarette packaging. Those precise words, and nothing else, were to be included. This Court held that tort claimants could not allege that Congress' language was inadequate to protect consumers.

[19] "[I]t would be particularly illogical to assume that Congress knew in 1976 when it drafted the MDA that the Supreme Court would interpret the word 'requirement' in 1992 in *Cipollone* to include common law tort claims." Adler & Mann, *supra*, 59 MO. L. REV. at 918. As Justice Breyer has commented, "[t]o change interpretive horses in midstream would defeat the expectations of the legislators who enacted a statute." Stephen Breyer, *On the Uses of Legislative History in Interpreting Statutes*, 65 S. CAL. L. REV. 845, 872 (1992).

This case presents no such issue. The FDA's role with respect to marketing notification pursuant to § 510(k) is merely to pass on the manufacturer's factual assertion that a new product is substantially *equivalent* to one already on the market. 21 U.S.C. § 360(k). Indeed, in 1982, when the § 510(k) notification for the Model 4011 lead was submitted, the MDA provided that the FDA was *not* required even to pass on Medtronic's claim of substantial equivalence and that a manufacturer like Medtronic was free to market its device 90 days after submission of the notification so long as it was not disapproved, even if the FDA did not respond to it. 21 U.S.C. § 360(k) (1982).

The § 510(k) process has always provided that the initial specifications for the design, manufacture, and labelling of the device are solely the responsibility of the manufacturer, which retains broad discretion in the matter. Thus, the FDA has declared that its acceptance of a claim of "substantial equivalence" does "not in any way denote official approval of the device," 21 C.F.R. § 807.97, and it repeated that disclaimer in the letter it issued to Medtronic. *See* App. to Br. for Lora and Michael Lohr at 10a.

Even as to devices that obtain premarket approval (PMA) pursuant to 21 U.S.C. § 360e(c)(1), the process is still very much driven and controlled by the manufacturer, which determines how the device is designed, labelled, and manufactured and which supplies all the clinical data and all the design, labelling, and manufacturing information upon which the FDA relies. Indeed, under the PMA procedure, the FDA does not mandate, or even approve, the device's design or specific manufacturing processes. *Kennedy v. Collagen Corp.*, 67 F.3d 1453, 1459 (9th Cir. 1995) ("it makes little sense to hold that the FDA's premarket approval process qualifies as a 'specific requirement applicable to a particular device'"). For this reason, the Department of Justice, representing the views of the FDA, has concluded that the PMA process does not establish "requirements" under § 360k(a) and, therefore, does not have

preemptive effect.[20]

A device manufacturer's safety-related undertakings do not resemble federal safety standards so much as they resemble the undertakings of a warrantor who determines what characteristics a product will have and who promises that the product will live up to those characteristics. In *Cipollone*, this Court held that an express warranty, because it was an undertaking of the manufacturer, was not a government requirement. 505 U.S. at 525-26. The same rationale applies in this case. *Cf. Rice v. Norman Williams Co.*, 458 U.S. 654, 659 (1982) ("The existence of a hypothetical or potential conflict is insufficient to warrant the preemption of the state statute.").

3. At bottom, the contention that government acquiescence in a particular manufacturer's design should insulate it from tort liability — even in the absence of an explicit congressional statement to that effect — is an argument about substantive social policy, not preemption law. In essence, the complaint is that a defendant should not be forced to compensate injured persons when the federal government has tacitly approved, or at least not forbidden, its conduct. But that argument proves too much, for almost every form of private activity in or affecting commerce could be described as something the government has chosen to permit or at least not to forbid.

More fundamentally, the defendant's plea is one that should be addressed to elected legislatures and politically accountable executive officers, not to the courts. The States should be free to decide, as a matter of distributive justice, that manufacturers should bear the cost of injuries resulting even from approved devices. In addition, immunizing a defendant from liability

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[20] *See* Br. of Dept. of Justice as *amicus curiae* in *Talbott v. C.R. Bard, Inc.*, No. 94-1951, at 14 n.5 (1st Cir.) (filed Nov. 23, 1994) (indicating disagreement with the decision in *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.), *cert denied*, 114 S. Ct. 84 (1993), and explaining that pre-market approval procedures are *not* "specific requirements" triggering preemption of state tort law).

whenever it obtains administrative approval for a particular design is a technology-based approach which is at odds with the contemporary preference for market-oriented incentives that continually stimulate manufacturers to innovate and develop safer products.[21] "When the courts preempt state laws without explicit congressional guidance, unelected and unaccountable officials substitute their preferences for those of the citizens of local communities. . . . [The courts] in effect assume a legislative role without accepting legislative responsibility." Judge Kenneth Starr & Judge Patrick E. Higginbotham, *et al.*, *The Law of Preemption: A Report of the Appellate Judges Conference* 48 (1991).

Preemption is all the more unjustified because state tort law has *already* accommodated the defendant's concern. It is axiomatic that standards set by federal agencies are useful benchmarks for the finders of fact in particular tort cases and that compliance with federal standards is at least evidence of due care. *See generally* Restatement (Second) of Torts § 288(c).[22] Some jurisdictions go further and mandate that compliance with such standards is a conclusive defense to tort liability, *see* Mont. Code Ann. § 69-4-201; establishes a rebuttable presumption of

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[21] *See* Steven Shavell, *Liability for Harm Versus Regulation of Safety*, 13 J. LEGAL STUD. 357, 359 (1984) (explaining that administrative regulation is a centralized system of government control, while tort law is essentially a market-based system that employs the expertise and information already accumulated by private firms in the ordinary course of their business); Stephen Breyer, REGULATION AND ITS REFORM 105 (1982) (design standards "diminish[] incentive[s] to look for better methods" and "freeze existing technology").

[22] *See also* Paul Deuffert, *The Role of Regulatory Compliance in Tort Actions*, 26 HARV. J. ON LEGIS. 175, 175 (1989) ("For a hundred years courts have considered axiomatic the common law principle that, against possible liability in tort, a defendant's compliance with governmental statutes and regulations is admissible only as evidence of the defendant's exercise of due care. Therefore, such compliance generally 'does not prevent a finding of negligence where a reasonable man would take additional precautions.'") (citations omitted).

non-negligence;[23] or bars punitive damages.[24]

In recent years, nearly every State has considered — and the vast majority have implemented — legislative reform of product liability laws.[25] As this brief is submitted, Congress itself is considering legislation on the topic. The matter should be left to the politically accountable branches. Preemption law should not become, as a weapon against the States' historic role in allocating the cost of injuries, the modern-day equivalent of *Lochner v. New York*, 198 U.S. 45 (1905).

III. THIS COURT SHOULD CLARIFY THE LIMITED SCOPE OF PREEMPTION DOCTRINE

In *Cipollone*, this Court corrected the Third Circuit's misapplication of implied preemption doctrine, based on the court of appeals' impressionistic judgment that tort suits would upset the "balance" struck by Congress in the cigarette warning statutes. Unfortunately, many lower courts have misinterpreted *Cipollone* by ignoring this Court's *holding* that the 1965 cigarette act did not preempt state-law suits, as well as this Court's statement that there is "no general, inherent conflict" between tort law and regulation. 505 U.S. at 518.

Instead, many lower courts have reacted to *Cipollone* by focusing solely on the plurality's discussion of the 1969 cigarette act, automatically equating tort suits and state positive-law enactments, and readily displacing *both* under the rubric of "express preemption." The error is not confined to the MDA

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[23] *E.g.*, Model Uniform Product Liability Act § 108(A); Colo. Rev. Stat. § 13-21-403(1)(b); 735 Ill. Ann. Stat. § 2-2103; Kan. Stat. Ann. § 60-3304(a); Ky. Rev. Stat. Ann. § 411.310(2); N.D. Cent. Code § 28-01.1-05(3); Utah Code Ann. § 78-15-6(3).

[24] *E.g.*, Ariz. Rev. Stat. Ann. § 12-701; N.J. Stat. Ann. § 2A:58C-5(c); Ohio Rev. Code Ann. § 2307.80(C); Or. Rev. Stat. § 30.927; Utah Code Ann. § 78-18-1.

[25] *See, e.g.*, *Tort Reform: Camel's Nose Into State Law*, NAT'L L.J., Mar. 20, 1995, at 1; *A Changing Landscape*, 81 ABA J. 56 (Aug. 1995).

context: lower courts have employed such fallacious reasoning in pesticide,[26] boat safety,[27] and other cases as well. As a result, express preemption threatens to become the sort of freewheeling analysis that this Court rejected in *Cipollone*. Another course correction to the lower courts is in order.

1. This Court should reaffirm that express preemption is limited to the text drafted by Congress, interpreted according to the conventional tools of statutory construction and with due regard for two fundamental principles.

The first is the strong presumption against preemption arising from the constitutional concerns of federalism rooted in the Tenth Amendment and in what the Chief Justice has described as "[t]he tacit postulates" of the constitutional plan. *Nevada v. Hall*, 440 U.S. 410, 433 (1979) (Rehnquist, now C.J., dissenting).[28]

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[26] *See, e.g.*, *Shaw v. Dow Brands, Inc.*, 994 F.2d 364, 371 (7th Cir. 1993) ("If common law actions cannot survive under the 1969 cigarette law, then common law actions for labeling and packaging cannot survive under the [pesticide] law."); *see also Welchert v. American Cyanamid, Inc.*, 59 F.3d 69, 73 (8th Cir. 1995); *Taylor AG Industries v. Pure-Gro*, 54 F.3d 555, 560 (9th Cir. 1995); *Worm v. American Cyanamid Co.*, 5 F.3d 744, 747-48 (4th Cir. 1993); *Papas v. Upjohn Co.*, 926 F.2d 1019, 1025-26 (11th Cir. 1991), *vacated*, 505 U.S. 1215 (1992), *on remand*, 985 F.2d 516, 517-18 (11th Cir.), *cert. denied*, 114 S. Ct. 300 (1993).

[27] *See, e.g.*, *Edwards v. Murray Chris-Craft Sportboats, Inc.*, 873 F. Supp. 618, 621 (M.D. Fla. 1994) (design claim expressly preempted — even in the face of a savings clause providing that "[c]ompliance with this chapter or standards, regulations, or orders prescribed under this chapter does not relieve a person from liability at common law or under State law" — because "[t]o allow a jury to award damages in this case under state common law for [defendant's failure] to incorporate positive flotation in the boat would be to establish, continue in effect, or enforce a law or regulation imposing a performance or other safety standard").

[28] *See, e.g.*, *Gregory v. Ashcroft*, 501 U.S. 452, 464 (1991) ("[I]nasmuch as this Court in *Garcia [v. San Antonio Metropolitan Transit Auth.*, 469 U.S. 528 (1985)] has left primarily to the political process the protection of the States against intrusive exercises of Congress' Commerce Clause powers, we must be absolutely certain that Congress intended such an exercise. '[T]o give

The second principle is that Congress legislates against a background understanding of the significant distinction between the tort and regulatory systems. Accordingly, a congressional decision to displace state positive-law enactments should not be equated with a decision to bar state-law tort suits for damages. Indeed, the presumption against preemption is especially strong when Congress has failed to provide a separate federal remedy for a person injured by tortious conduct, as in the MDA.

2. This Court should also reaffirm the limited scope of implied preemption and reject the analysis proffered by Medtronic at 46 n.24 of its brief. When Congress has expressly addressed the matter of preemption in a specific statutory provision whose meaning can be ascertained through the conventional tools of statutory construction — applied with reference to the two principles outlined above — preemption analysis should ordinarily be at an end. *See Freightliner Corp. v. Myrick*, 115 S. Ct. 1483, 1488 (1995) (establishing "an inference that an express pre-emption clause forecloses implied pre-emption").

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the state-displacing weight of federal law to mere congressional *ambiguity* would evade the very procedure for lawmaking on which *Garcia* relied to protect states' interests.'") (quoting Laurence Tribe, AMERICAN CONSTITUTIONAL LAW § 6-25, at 480 (2d ed. 1988)); *see also U.S. Term Limits, Inc. v. Thornton*, 115 S. Ct. 1842, 1887 n.12 (1995) (Thomas, J., joined by Rehnquist, C.J., and O'Connor and Scalia, JJ., dissenting) (quoting the same sentence of AMERICAN CONSTITUTIONAL LAW and describing *Gregory* as "applying this argument"); Judge Kenneth Starr & Judge Patrick E. Higginbotham, *et al.*, *The Law of Preemption: A Report of the Appellate Judges Conference* 50-51 (1991) (discussing plain statement requirement in preemption context).

CONCLUSION

The judgment of the Court of Appeals should be reversed insofar as it holds that the MDA preempts any of the state-law claims for damages asserted by respondents/cross-petitioners Lora and Michael Lohr.

Respectfully submitted.

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